EXHIBIT B

Supplemental Expert Report of Dr. Stephen Spiegelberg
Ph.D., Chemical Engineering

June 2, 2014

I. INTRODUCTION

Since signature and submission of my previous expert reports, Chevron Phillips Chemical Company ("CP Chem") produced a corporate representative, Frank Zakrzewski, for deposition concerning Phillips Sumika's manufacture of Marlex HGX-030-01 polypropylene resin. Mr. Zakrzewski is currently the procurement operations manager for CP Chem. Specifically, Mr. Zakrzewski's deposition provides additional support for two of my opinions:

- The Medical Application Caution in the Material Safety Data Sheet for Marlex HGX-030-01 polypropylene resin has no scientific or medical basis.
- The Advantage and Polyform meshes comprising Boston Scientific's pelvic mesh devices contains two different antioxidants, which further supports my opinion that the BSC mesh does not undergo oxidative degradation *in vivo*.

Also, testing and analysis has been completed comparing a sample of Marlex HGX-030-01 polypropylene resin to a sample of Ineos H03G-02 polypropylene resin. The safety data sheet for the Ineos polypropylene resin does not contain any caution against human use. The testing results indicate that the two polypropylene resins are near identical in various measurements of molecular weight. This further confirms the safety and appropriateness of use of the Marlex HGX-030-01 polypropylene resin in Boston Scientific's Advantage and Polyform meshes.

II. OPINIONS

A. The MSDS Medical Application Caution Has No Scientific Basis

As I have stated previously, there is no evidence that the MSDS Medical Application Caution was added based on any scientific concerns with the safety of the polypropylene resin.

Indeed, Mr. Zakrzewski testified that the statement *was not* added based on scientific testing, data, or literature on polypropylene – and that the statement is not unique to polypropylene MSDSs. (54:19-55:1). During his corporate representative deposition, Mr. Zakrzewski testified that the medical application statement was not added based on: scientific testing (45:24-46:5, 64:22-65:4, 66:8-13, 183:9-14); scientific data (46:6-11); any scientific basis (184:11-14); review of any scientific or medical literature (47:8-15); or scientific concerns with vaginal mesh (47:16-21).

Further, as stated by Mr. Zakrzewski, the Medical Application Caution is not located in the "hazards section" of the MSDS. (54:15-18). As discussed in my initial report, the Marlex MSDS provides no scientific evidence of a health hazard associated with permanent implantation; indeed, the health hazard classification for Marlex HGX-030-01 is zero. (65:22-66:7). Further, according to the Globally Harmonized System Classification, which has now been adopted by OSHA, Marlex HGX-030-01 is "[n]ot a dangerous substance according to the globally harmonized system of classification and labeling of chemicals." (188:5-12).

Mr. Zakrzewski also explained that Phillips Sumika did not "determine suitability of use" because their "expertise is in producing resin, and there are steps between resin and a final product…[they're] not experts in processing. [They're] not experts in determining how someone wants to use [the] product." (107:8-10, 15-20). Mr. Zakrzewski explained that Phillips Sumika expected the end processor, Boston Scientific, to determine the suitability of use of Marlex resin for its application. (168:20-24). This is in part because Phillips Sumika has no medical device expertise, but are simply a "resin manufacturer." (173:13-19). Further, Mr. Zakrzewski testified that there was an agreement between Boston Scientific and Phillips Sumika that the polypropylene resin may be used "by, for or on behalf of Boston Scientific in the manufacture of

medical devices which may be implanted in the human body or have contact with internal body fluids or tissues." (71:1-8, 13-14). And Phillips Sumika understood that "distributors" and "third parties", not just "end manufacturers," would purchase resin. (144:4-8, 167:11-168:1).

Mr. Zakrzewski explicitly testified that there was no scientific basis, data, or testing of the polypropylene when revising the MSDS in 2004, and that CP Chem did not add the statement based on any scientific or medical concerns with transvaginal mesh. Further, he testified that CP Chem does not determine suitability of use, but leaves that determination to the end user. As I have previously explained, Boston Scientific as the "end use" user appropriately determined that the Marlex HGX-030-01 polypropylene resin was "suitable for use" in its Advantage and Polyform meshes. Boston Scientific performed a battery of ISO 10993 biocompatibility testing at various points in time, the results of which demonstrate that the material is safe for permanent use in the human body. The extensive leaching studies performed by Boston Scientific on the finished polypropylene mesh demonstrate that there are no biological responses to any potential leachable materials. Moreover, Boston Scientific conducted mechanical testing on its pelvic mesh products to ensure the products were able to perform as intended. In addition to Boston Scientific's ISO 10993 and mechanical testing, the use of polypropylene in the human body is supported by a long history of safe and effective use in various medical applications, including use as a surgical mesh.

This history of safe use has been recognized by leading medical organizations for the treatment of female pelvic floor disorders. AUGS and SUFU issued a January 2014 position statement stating, "Polypropylene material is safe and effective as a surgical implant. Polypropylene material has been used in most surgical specialties (including general surgery, cardiovascular surgery, transplant surgery, ophthalmology, otolaryngology, gynecology, and

urology) for over five decades, in millions of patients in the US and the world . . . . As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, light weight polypropylene has demonstrated long term durability, safety, and efficacy up to 17 years."[1]

B. BSC's Pelvic Mesh Devices Will Not Undergo Oxidative Degradation *In Vivo*

According to the deposition testimony of Mr. Zakrzewski, Marlex HGX-030-01 polypropylene resin contains three additives: Irganox 3114, Irgafos 168, and DHT-4A. (178:7-19, 178:24-179:8). Irganox and Irgafos are common, well-known antioxidants used in the manufacture of polymers, such as the polypropylene utilized in monofilament mesh.[2] Antioxidants are added to polypropylene resin to stabilize the resin during thermal processing (e.g. extrusion) and help ensure finished product durability in its application area. Irganox 3114 is a high extraction-resistant[3] primary antioxidant which acts as a free radical scavenger, therefore inhibiting oxidation from occurring. Irganox 3114 provides long-term protection to the polypropylene. Irgafos 168 is a secondary antioxidant, which act by converting hydroperoxide into stable species. Secondary antioxidants provide process stabilization by prevention of thermo-oxidation during polymer processing. The secondary antioxidant protects the primary antioxidant during thermal processing, resulting in the continued presence of the antioxidants in the finished product. DHT-4A is a common polymer additive that is an acid scavenger and process stabilizer.

The presence of both a primary and secondary antioxidant in the polypropylene resin provides further support for my opinion that Boston Scientific's polypropylene mesh will not

---

[1] AUGS/SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence (issued January 2014).

[2] As stated in the CP Chem deposition: "All raw materials used in the manufacture of the Marlex HGX-030-01 meet the standards of the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated." (151:8-14, 23-152:3).

[3] BASF Additives for Specialty Polymers.

undergo clinically significant oxidative degradation *in vivo*. The presence of these two antioxidants would counteract any alleged oxidative degradation of Boston Scientific polypropylene mesh in the human body. Further, as explained in my previous reports, there is no scientific evidence of clinically significant oxidative degradation.

C. Marlex HGX-030-01 is Safe for Permanent Use in the Human Body

In gel permeation chromatography testing performed by a German polymer lab, the results confirm that Marlex HGX-030-01 polypropylene resin has a very similar molar mass distribution as Ineos H03G-02 polypropylene resin, with number, weight, and z-average molar masses of the two resin within 12% of each other for each molar mass moment. Both resins show a uni-modal distribution curve, with comparable lower molar mass tails. Ineos H03G-02 is a homopolymer polypropylene resin. The product data sheet for this resin indicates that it has a comparable melt flow rate and similar tensile strength at yield, flexural modulus, heat deflection temperature, and Izod impact strength as the Marlex HGX-030-01 resin.[4] The Ineos resin material safety data sheet contains no caution, statement, or warning about using the resin in permanent medical applications.[5]

The near identical molar mass distributions of these two polypropylene resins indicate that they have the same polypropylene chain lengths, which will result in very similar mechanical performance, which is confirmed by the performance data sheets for the two polymers. The two polypropylenes would perform equivalently in the human body based on the molar mass distribution. This analysis supports my opinion that the Marlex MSDS medical statement has no scientific or safety-mandated purpose, as an identical resin's MSDS does not contain any such statement. Marlex HGX-030-01 is safe for use in permanent implants, in

[4] Ineos H03G-02 Polypropylene Resin Product Data Sheet; Marlex HGX-030-01 Product Data Sheet.
[5] Ineos H03G-02 Polypropylene Resin Material Safety Data Sheet.

particular, in Boston Scientific's Advantage and Polyform meshes.

Dated: 6/2/2014

By _____
Stephen Spiegelberg, Ph.D.

EXHIBIT A

DR. STEPHEN SPIEGELBERG
SUPPLEMENT TO
ADDITIONAL MATERIALS CONSIDERED FOR
EXPERT REPORT

1. Ostergard, Donald R. – "To mesh or not to mesh with polypropylene: does carcinogenesis in animals matter?" *Int Urogynecol J, 2014*
2. Moalli, Pamela, et al. – "Polypropylene mesh: evidence for lack of carcinogenicity" *Int Urogynecol J 2014*
3. Williams, David F. – "Carcinogenicity of implantable materials: experimental and epidemiological evidence" *Int Urogynecol J 2014*
4. Dwyer, P.L., et al. – "Carcinogenicity of implanted synthetic grafts and devices" *Int Urogynecol J 2014*
5. Deposition of Russell Dunn